

## 2018 Current Fiscal Year Report: Scientific Advisory Committee on Alternative Toxicological Methods

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### 1. Department or Agency

Department of Health and Human Services

### 2. Fiscal Year

2018

### 3. Committee or Subcommittee

Scientific Advisory Committee on Alternative Toxicological Methods

### 3b. GSA Committee No.

12153

### 4. Is this New During Fiscal Year?

No

### 5. Current Charter

12/18/2017

### 6. Expected Renewal Date

12/18/2019

### 7. Expected Term Date

### 8a. Was Terminated During Fiscal Year?

No

### 8b. Specific Termination Authority

### 8c. Actual Term Date

### 9. Agency Recommendation for Next Fiscal Year

Continue

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority

Statutory (Congress Created)

### 12. Specific Establishment Authority

42USC 285I-3(d)

### 13. Effective Date

12/19/2000

### 14. Committee Type

Continuing

### 14c. Presidential?

No

### 15. Description of Committee

Scientific Technical Program Advisory Board

### 16a. Total Number of Reports

No Reports for this Fiscal Year

### 17a. Open Meetings and Dates

#### Purpose

Scientific and Technical Program Advisory

#### Start

09/05/2018

#### End

- 09/06/2018

### Number of Committee Meetings Listed: 1

|   | Current FY  | Next FY     |
|---|-------------|-------------|
| 18a(1). Personnel Pmts to Non-Federal Members         | \$3,600.00  | \$3,600.00  |
| 18a(2). Personnel Pmts to Federal Members             | \$0.00      | \$0.00      |
| 18a(3). Personnel Pmts to Federal Staff               | \$63,361.00 | \$64,561.00 |
| 18a(4). Personnel Pmts to Non-Member Consultants      | \$3,200.00  | \$3,200.00  |
| 18b(1). Travel and Per Diem to Non-Federal Members    | \$8,110.00  | \$8,215.00  |
| 18b(2). Travel and Per Diem to Federal Members        | \$0.00      | \$0.00      |
| 18b(3). Travel and Per Diem to Federal Staff          | \$0.00      | \$0.00      |
| 18b(4). Travel and Per Diem to Non-member Consultants | \$9,660.00  | \$9,796.00  |

|   |             |              |
|---|-------------|--------------|
| <b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b> | \$11,500.00 | \$11,730.00  |
| <b>18d. Total</b>   | \$99,431.00 | \$101,102.00 |
| <b>19. Federal Staff Support Years (FTE)</b>                          | 0.40        | 0.40         |

**20a. How does the Committee accomplish its purpose?**

The scope and objectives of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) are to advise the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, and national and international harmonization of new, revised, and alternative toxicological test methods. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties. SACATM met on September 5-6, 2018, at NIEHS. A major focus of the meeting was implementation on the A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States. SACATM heard presentations on challenges to and opportunities for implementing non-animal approaches, with skin sensitization and acute toxicity testing as examples. The committee was asked to provide input on proposed new approaches to validation, including efforts underway by the Organisation for Economic Co-operation and Development, appropriate acceptance criteria for in-vitro and in silico techniques, and how animal data might be used to evaluate the performance of new approach methodologies. Data collection and data sharing were also topics for presentation and discussion by SACATM including a machine learning project to identify high quality studies, updates to the Integrated Chemical Environment-a database of high quality, curated data. SACATM was also asked to provide input on a proposal for developing a sustainable, open-source repository of toxicology data that would enable data sharing while protecting confidential and proprietary information. Meeting information can be found at <http://ntp.niehs.nih.gov/go/32822>.

**20b. How does the Committee balance its membership?**

Members are selected from recognized authorities knowledgeable in academia, industry, state government, public health, environmental communities or organizations using new or alternative test methods, as appropriate, in accordance with the statutorily mandated requirements for representation on the SACATM.

### **20c. How frequent and relevant are the Committee Meetings?**

Meetings are held at least once each fiscal year. The NIEHS Director appoints voting members to the SACATM, and membership is defined in the ICCVAM Authorization Act of 2000 to include representatives from academia, state government, industry, and animal protection organizations.

### **20d. Why can't the advice or information this committee provides be obtained elsewhere?**

The quality, scope and balance of advice provided cannot be obtained from NIH staff or from other established sources. Its membership is constituted to meet the specific requirements of the mandated mission of the committee and the Institute.

### **20e. Why is it necessary to close and/or partially closed committee meetings?**

NA

### **21. Remarks**

The DFO and Committee Decision Maker positions are held by the same individual due to the assignment of responsibilities within this Institute. This committee did not produce any reports this fiscal year. According to the charter language NIH has determined there are technically 11 ex officio positions associated with this committee and the max number of positions has been modified to include these members. No ex officio members have been identified and there are no ex officio members in the list of current members in this report. It has been the practice of ICCVAM members to send ad hoc attendees according to the topics being discussed rather than having ex officio members formally identified.

Members: Drs. William Janzen and Wei Xu were extended one year as per the charter, which allows for extensions until replacement. Dr. Brian Berridge resigned in January 2018 before the end of his appointed term. Dr. Pamela Spencer's term as member will end 11/30/2018 and she will be reassigned as Chair on December 1, 2018.

### **Designated Federal Officer**

MARY S WOLFE DEPUTY DIVISION DIRECTOR FOR POLICY

| <b>Committee Members</b> | <b>Start</b> | <b>End</b> | <b>Occupation</b>                            | <b>Member Designation</b>                |
|--------------------------|--------------|------------|--|--|
| BERRIDGE, BRIAN          | 02/07/2016   | 01/06/2018 | DIRECTOR, WW ANIMAL RESEARCH STRATEGY        | Special Government Employee (SGE) Member |
| BOLGER, MICHAEL          | 12/11/2016   | 11/30/2020 | CHIEF SCIENTIST                              | Special Government Employee (SGE) Member |
| COLEMAN, KELLY           | 12/11/2016   | 11/30/2020 | DISTINGUISHED SCIENTIST AND TECHNICAL FELLOW | Special Government Employee (SGE) Member |
| HAMADEH, HISHAM          | 12/01/2015   | 11/30/2019 | DIRECTOR                                     | Special Government Employee (SGE) Member |
| JANZEN, WILLIAM          | 08/10/2014   | 11/30/2018 | EXECUTIVE DIRECTOR OF LEAD DISCOVERY         | Special Government Employee (SGE) Member |

|                            |            |            |  |  |
|----------------------------|------------|------------|--|--|
| MILCHAK, LAWRENCE          | 12/01/2015 | 11/30/2019 | SENIOR MANAGER                                 | Special Government Employee (SGE) Member |
| SPENCER, PAMELA            | 02/07/2016 | 11/30/2018 | DIRECTOR OF REGULATORY AND PRODUCT STEWARDSHIP | Special Government Employee (SGE) Member |
| WILLETT, CATHERINE         | 08/10/2014 | 11/30/2017 | DIRECTOR                                       | Special Government Employee (SGE) Member |
| WILLIAMS-DEVANE, CLARLYNDA | 12/11/2016 | 11/30/2020 | DIRECTOR                                       | Special Government Employee (SGE) Member |
| XU, WEI                    | 08/10/2014 | 11/30/2018 | ASSOCIATE PROFESSOR                            | Special Government Employee (SGE) Member |
| ZHU, HAO                   | 02/07/2016 | 11/30/2019 | ASSISTANT PROFESSOR                            | Special Government Employee (SGE) Member |

**Number of Committee Members Listed: 11**

### Narrative Description

This committee advises the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicology Methods (Center) regarding ICCVAM activities. They also advise the NIEHS and the NTP Center on the NTP Center's activities.

### What are the most significant program outcomes associated with this committee?

Checked if Applies

|   |                                     |
|---|-------------------------------------|
| Improvements to health or safety                  | <input checked="" type="checkbox"/> |
| Trust in government                               | <input checked="" type="checkbox"/> |
| Major policy changes                              | <input type="checkbox"/>            |
| Advance in scientific research                    | <input checked="" type="checkbox"/> |
| Effective grant making                            | <input type="checkbox"/>            |
| Improved service delivery                         | <input type="checkbox"/>            |
| Increased customer satisfaction                   | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input type="checkbox"/>            |
| Other   | <input type="checkbox"/>            |

### Outcome Comments

NA

### What are the cost savings associated with this committee?

Checked if Applies

|                       |                                     |
|-----------------------|-------------------------------------|
| None                  | <input type="checkbox"/>            |
| Unable to Determine   | <input checked="" type="checkbox"/> |
| Under \$100,000       | <input type="checkbox"/>            |
| \$100,000 - \$500,000 | <input type="checkbox"/>            |

\$500,001 - \$1,000,000  
\$1,000,001 - \$5,000,000  
\$5,000,001 - \$10,000,000  
Over \$10,000,000  
Cost Savings Other

☐  
☐  
☐  
☐  
☐

### **Cost Savings Comments**

Many of the alternative test methods promoted by SACATM may in theory reduce the cost of individual toxicity tests, but it is unclear whether reduced cost per agent tested will be offset by increasing number of agents tested.

**What is the approximate Number of recommendations produced by this committee for the life of the committee?**

59

### **Number of Recommendations Comments**

0

**What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?**

0%

### **% of Recommendations Fully Implemented Comments**

Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

0%

### **% of Recommendations Partially Implemented Comments**

Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

### Agency Feedback Comments

Staff identifies key outcomes of the meeting and reports back to SACATM at the next meeting on developments on the recommendations or advice (either by formal presentation or during discussion).

### What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities

☐

Reallocated resources

☐

Issued new regulation

☐

Proposed legislation

☐

Approved grants or other payments

☐

Other

☒

### Action Comments

The Committee makes recommendations to federal staff regarding the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties.

### Is the Committee engaged in the review of applications for grants?

No

### Grant Review Comments

NA

### How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO

☒

Online Agency Web Site  
Online Committee Web Site  
Online GSA FACA Web Site  
Publications  
Other



**Access Comments**

N/A